EUROPEAN COMMISSION

SECRETARIAT-GENERAL

Brussels, 26 XII 2005

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BY COURIER SERVICE

Bristol – Myers Squibb Pharma EEIG
Uxbridge Business Park
Sanderson Road
Uxbridge UD8 1DH - UK

Subject: NOTIFICATION PURSUANT TO ARTICLE 254 OF THE EC TREATY

The enclosed Decision is transmitted to the Member States.

For the Secretary-General

Karl VON KEMPIS

Encl.: C(2005) 5975

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 23-XII-2005
C(2005)5975

NOT FOR PUBLICATION

COMMISSION DECISION

of 23-XII-2005

relating to the designation under Regulation (EC) No 141/2000 of the European Parliament and of the Council of "Dasatinib" as an orphan medicinal product

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 23-XII-2005

relating to the designation under Regulation (EC) No 141/2000 of the European Parliament and of the Council of "Dasatinib" as an orphan medicinal product

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[1], and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 25 August 2005 under Article 5(1) of Regulation (EC) No 141/2000,

Having regard to the favourable opinion of the European Medicines Agency, drawn up on 10 November 2005 by the Committee for Orphan Medicinal Products and received by the Commission on 23 November 2005,

Whereas:

(1) The application submitted by Bristol-Myers Squibb Pharma EEIG concerning the medicinal product "Dasatinib" was validated on 12 September 2005 under Article 5(4) of Regulation (EC) No 141/2000.

(2) "Dasatinib" meets the designation criteria referred to in Article 3(1) of Regulation (EC) No 141/2000.

(3) The application should therefore be accepted,

HAS ADOPTED THIS DECISION:

Article 1

The medicinal product "Dasatinib" is designated as an orphan medicinal product for the indication: Treatment of chronic myeloid leukaemia. It shall be entered in the Community Register of Orphan Medicinal Products under No EU/3/05/339.

[1] OJ L 18, 22.1.2000, p.1.

Article 2

The European Medicines Agency shall make available to all interested parties the opinion of the Committee on Orphan Medicinal Products referred to in this Decision.

Article 3

This Decision is addressed to Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge UD8 1DH, United Kingdom.

Done at Brussels, 23-XII-2005

For the Commission
Günter VERHEUGEN
Vice-President of the Commission

COMMISSION OF THE EUROPEAN COMMUNITIES

CERTIFIED COPY
For the Secretary - General,

Jordi AYET PUIGARNAU
Director of the Registry